

# Hyaluronic acid gel improves wound healing in diabetic patients after digit amputations

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## PURPOSE

Foot ulceration and amputation are common, multi-factorial and costly complications in patients with diabetes [1,2]. Upwards of 85% of amputations are preceded by foot ulcers [3], and those patients with a lower extremity amputation have a diminished quality of life [4]. The healing of digit amputations is not often predictable and its complications are an important cause of morbidity and mortality in patients with diabetes [5]. In recent years, major advances in wound treatment have developed, however, a high prevalence of non-healing wounds still persists. Therefore, it is vital to treat these wounds with advanced wound dressings that can accelerate wound healing and decrease comorbidities.

The purpose of this study was to evaluate the time to heal in diabetic patients with digit amputations treated with a sodium hyaluronate (2.5%) wound gel [6] from January 1<sup>st</sup> to July 31<sup>st</sup>, 2015.

## METHODS

After digit amputations, patients received the hyaluronic acid gel treatment daily until incision line was healed. Every week, photographs of incision lines were taken. Time to heal for surgical incisions was defined as the time it took for the sutures to be removed.



## RESULTS

Our results demonstrated that the time to heal in those patients receiving hyaluronic acid gel after performing digit amputations was predominantly within 2 weeks. This is in contrast to a typical 4 week healing time that we observed prior to using HA gel. In addition, our complication rate was correspondingly low as we were not dealing with incision line dehiscence or infection.

## CONCLUSIONS

The results showed that HA gel may improve the time to heal of the incision lines compared to those treated with standard of care and reduces complication rates by introducing this product as a postoperative treatment protocol.

## ACKNOWLEDGEMENTS

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## References

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# The Use of 2.5% Sodium Hyaluronate Wound Gel

## to Promote Wound Healing for Patients with Diabetic Foot Ulcers (DFUs) and Lower Leg Ulcers (LLUs) in Community Settings by a Certified Wound Ostomy Continence Nurse (CWOCN)

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### Background

- Reducing health care costs has been acknowledged as a global issue.
- “Every 30 seconds a lower limb is lost due to diabetes somewhere in the world”.
- 50% patients with leg ulcers had a leg ulcer history 5 to 10 years; 30% > 10 years.
- Treatment costs increaseswhen the duration of treatment, and product use increase.
- Early identification of difficult-to-heal wounds and targeted use of advanced wound care products should be considered whenever possible (Vowden 2011).

### 2.5% Sodium Hyaluronate Wound Gel

Has been used for management of lower leg ulcers, pressure ulcers, diabetic foot ulcers, and surgical wounds (Reece & Quiring, 2002; Woo, et al 2005).

### Method (Study period: May – November 2016)

This prospective, self-controlled non-randomized clinical case series study was conducted to evaluate the efficacy of 2.5% sodium hyaluronate wound gel for community patients with DFUs or LLUs in out-patient clinic settings by assessing:

- The healing rates by comparing the changes of wound size and time to heal
- The incidence of complications

### Inclusive Criteria

- Wounds that failed to reduce size by 30% after treatment for 4 weeks
- DFU: of wound size <10 cm<sup>2</sup>; have been off-loaded with most appropriate offload device, Total Contact Cast (TCC), Poor Man TCC, iTCC, etc.
- LLUs of wound size <100 cm<sup>2</sup>
- Patient with LLUs that have been on 20 mmHg or more compression therapy

### Study Protocol (Weekly wound gel treatment till wound closed or a max. 27 weeks)

- Sharp or mechanical wound debridement by the Principal Investigator, a CWOCN
- Applied wound gel liberally to wound base and margins
- Maintained moisture/bacterial balance with bacterial binding dressings to
- Continued with appropriate offload (DFUs) or compression (LLUs)

### References:


- Reece, et al. (2002) Hyaluronic acid in an ionic polymer gel matrix helps create an optimal environment for ulcer healing. Poster presentation, SAWC Conference, Apr 2002.
- Sibbald et al (2011). Special Consideration in Wound Bed Preparation. *Advances in Skin and Wound Care*, Sept 2011, pp. 425–436
- Vowden (2011). Hard-to-heal Wounds Made Easy. *Wounds International* 2011; 2(4), pp. 1 – 6. <http://woundsinternational.com>

Results: 33 patients recruited; 20 patients completed the study (10 DFU (50%); 10 LLUs (50%):

- 8 patients (40%): wounds closed
- 9 patients (45%): wounds improved
- 3 patients (15%): wound status undetermined
- Mean Home Care Nurse treatment days before PI treatment: 195 days
- Mean PI treatment days before wound gel treatment: 193 days
- Mean wound gel weekly applications 15 weeks (105 days)

### Implications:

- The results supported the use of the wound gel to supplement standard wound treatment for patients with DFUs or LLUs.
- To provide stronger evidence, further studies with a larger sampling size with follow up assessments in 3, 6 and 12 months to evaluate the recurrence rates is recommended.

Case 1					Case 2				
									
August 5, 2015	May 25, 2016 1 <sup>st</sup> wound gel on 290 days PI treatment	July 14, 2016 4 <sup>th</sup> week wound gel	Nov 30, 2016 20 <sup>th</sup> week wound gel		March 14, 2016 1 <sup>st</sup> PI Treatment	May 31, 2016 Wound infected requiring IV antibiotics	July 26, 2016 3 <sup>rd</sup> TCC Offloader + 1 <sup>st</sup> wound gel	Aug 16, 2016 6 <sup>th</sup> TCC Offloader + 4 <sup>th</sup> wound gel	Nov 14, 2016 After 13 <sup>th</sup> wound gel + TCC Poor Man
6 cm x 4.2 cm = 25.4 cm <sup>2</sup>	4 cm x 2.4 cm = 9.6 cm <sup>2</sup>	3 cm x 2.5 cm = 7.5 cm <sup>2</sup>	1.5 cm x 0.7 cm = 1.05 cm <sup>2</sup>		0.4 cm x 0.3 cm = 0.12 cm <sup>2</sup>	2.1 cm x 1 cm = 2.1 cm <sup>2</sup>	2 cm x 1.5 cm = 3 cm <sup>2</sup>	1.3 cm x 1.2 cm = 1.56 cm <sup>2</sup>	Wound Closed
					0.3 cm deep with undermining				

Case 3					Case 6				
									
Aug 25, 2016 TCC Poor Man + 1 <sup>st</sup> Wound gel	September 22, 2016 3 <sup>rd</sup> TCC Offloader + 2 <sup>nd</sup> Wound Gel	Sept 29, 2016 4 <sup>th</sup> TCC Offloader + 3 <sup>rd</sup> Wound Gel	Oct 17, 2016 5 <sup>th</sup> TCC Offloader + 5 <sup>th</sup> Wound Gel	Nov 7, 2016 After 7 <sup>th</sup> TCC Offloader and 7 <sup>th</sup> Wound Gel	August 1, 2015 1 <sup>st</sup> PI Treatment	Dec 22, 2015 11 <sup>th</sup> PI Treatment	May 6, 2016 1 <sup>st</sup> IPM Wound Gel (Post 27 <sup>th</sup> 250 days PI treatment)	June 24, 2016 8 <sup>th</sup> Wound Gel	Nov 4, 2016 Post 22 <sup>nd</sup> Wound Gel
1 cm x 0.5 cm = 0.5 cm <sup>2</sup>	0.5 cm x 0.8 cm = 0.5 cm <sup>2</sup>	0.5 cm x 0.8 cm = 0.5 cm <sup>2</sup>	1.5 cm x 0.5 cm = .75 cm <sup>2</sup>	1.5 cm x 0.5 cm = .75 cm <sup>2</sup>	Bacterial Binding dressings started		Deep Small Wound	Wound size ↑ Depth ↓	Patient was discharged after
(0.5 cm deep with undermining 0.5 cm 12 – 12 o'clock)	Deep sinus 3 cm @ 9 o'clock	Deep sinus 2.5 cm @ 9 o'clock	Sinus 0.3 cm @ 9 o'clock	Wound closed	1.5 cm x 0.9 cm = 1.35 cm <sup>2</sup>	2 cm x 1 cm = 2 cm <sup>2</sup>	0.9 cm x 0.6 cm = 0.54 cm <sup>2</sup> (0.4 cm deep)	100% granulation 1 cm x 0.8cm = 0.8 cm <sup>2</sup> (0.2 cm deep)	Wound Closed on Sept 30, 2016

### Disclaimer

- This study was unfunded. The vendor provided the 2.5% sodium hyaluronate wound gel for 20 selected patients for product evaluation.
- The trade name of this 2.5% sodium hyaluronate wound gel is GlycoBioSciences Inc. IPM™ Wound Gel Bio.